EMBOLECTOMY DEVICE

Field of the Invention

The present invention relates generally to the field of intravascular devices. More specifically, the present invention pertains to embolectomy devices for aspirating foreign bodies within a body lumen.

Background of the Invention

There are a number of situations in the practice of medicine where it is desirable to remove an embolus from a patient's vasculature. If an embolus is not removed it may travel to the neural vasculature, for example, and cause severe trauma. Many prior art embolectomy devices require a retrieval portion to be placed downstream or distal the embolus. This is not always practical or desirable. Other prior art embolectomy devices may require the use of a significant vacuum to remove the embolectomy. This may cause the collapse of a portion of the vasculature and result in trauma.

Summary of the Invention

In one embodiment of an embolectomy device, a first catheter having an expandable tip may be disposed inside of a second catheter which constrains the tip. The proximal end of either the first or second catheters may be fluidly attached to a vacuum source. The tip may be expanded by moving the first catheter distally relative the second catheter. An embolus may then be urged into the tip by operating the vacuum source.

In another embodiment of an embolectomy device, a first catheter having an expandable tip may be disposed inside of a second catheter which constrains the tip. A

clot pulling device may be disposed within the second catheter. The tip may be expanded by moving the first catheter distally relative the second catheter. The clot pulling device may be operated to urge an embolus into the expanded tip.

In another embodiment, a clot unclogging or fragmenting device may be disposed in a catheter, which may be fluidly connected to a vacuum source. The unclogging or fragmenting device may be connected to a motion control apparatus by a wire disposed in a lumen of the catheter. The unclogging or fragmenting device may be operated to open the tip of a catheter blocked by the clot burden or to fragment an embolus, which may then be drawn into a catheter lumen by operation of the vacuum source. The catheter may have a lumen connected to an irrigation source.

The above summary of some embodiments is not intended to describe each disclosed embodiment or every implementation of the present invention. The figures and detailed description which follow more particularly exemplify these embodiments.

Brief Description of the Drawings

The invention may be more completely understood in consideration of the following detailed description of various embodiments of the invention in connection with the accompanying drawings in which:

Figure 1a depicts an embolectomy device 300 disposed in a body lumen.

Figure 1b depicts an embolectomy device 400 disposed in a body lumen.

Figure 1c depicts an embolectomy device 500 disposed in a body lumen.

Figure 2a depicts a retrieval catheter 204 of embolectomy device 200.

Figure 2b depicts a guide catheter 206 of embolectomy device 200.

Figure 2c depicts embolectomy device 200.

Figure 2d depicts embolectomy device 200.

Figure 3 depicts an embolectomy device 100 disposed in a vascular lumen.

Detailed Description

The following detailed description should be read with reference to the drawings, in which like elements in different drawings are numbered identically. The drawings which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention.

Figure 1a depicts an embolectomy device 300 disposed in a body lumen. Device 300 includes catheter 302 and distal device 304. Distal device 304 may be used to unclog the aspiration lumen or to fragment an embolus for aspiration. Catheter 302 may have a manifold 306 attached proximally including a first port 308 and a second port 310. Distal device 304 has a proximal end 312 attached to an elongate member 314 disposed in a lumen of catheter 302. Distal device 304 may have an arcuate shape, or may be formed into a loop, coil, paddle, whisk, zigzag, helical or other shape suitable for fragmenting an embolus. The proximal end of elongate member 314 may be free or may be attached to a motion control apparatus able to impart motion along the axis of elongate member 314. The motion control apparatus may impart longitudinal or radial motion or vibration to the distal end of elongate member 314. Catheter 302 may also be fluidly attached to a vacuum source.

The motion control apparatus may impart a motion to distal device 304 at between 1 Hz and 150 Hz. Of course, motion at higher or lower frequencies than this are envisioned. As an example, it may be advantageous to move distal device 304 at selective intervals lower than 1 Hz only when a lumen is clogged. In addition, it may be preferable to impart a motion at up to 20 kHz. The motion control apparatus may have any advantageous range of motion. One example range of motion is 17 mm. This may

be done by configuring the motion control apparatus to move distal device 2 mm proximally and 15 mm distal from a starting position. Another example range of motion is 120 mm, with the motion control apparatus configured to move distal device 304 20 mm proximally and 100 mm distally.

Figure 1b depicts an embolectomy device 400. Device 400 is similar to device 300 and includes a catheter 402 having an angled distal end 418.

Figure 1c depicts an embolectomy device 500. Device 500 is similar to device 300 and includes a first lumen 520 and a second lumen 522. Elongate member 314 is disposed in first lumen 520 and the vacuum source is fluidly connected to second lumen 522. In use, embolectomy device 500 may be positioned proximate an embolus and the vacuum source may be operated. Distal device 304 may be operated, either by hand or through a motion control apparatus to unclog an aspiration or other lumen or to fragment an embolus. Distal device 304 may thereby fragment the embolus and the embolus or one or more fragments thereof is drawn into second lumen 522. Distal device 304 may alter the shape of an embolus and unclog a lumen or fragment the embolus through vibrations or pulses at the distal end of elongate member 314. In an alternative use, fluid may be irrigated through first lumen 520 or through an additional lumen. Distal device 304 may alternatively or additionally be used to unclog an embolus from a lumen by removing the embolus burden and thereby creating an open channel for more effective aspiration

Figure 2c depicts embolectomy device 200, which includes retrieval sheath 204 and guide catheter 206. As depicted in Figure 2a, retrieval sheath 204 may include an expandable elongate shaft or elongate shaft 208 and expandable tip portion 210.

Expandable tip portion may be formed from a shape memory polyurethane, a nitinol coiled sheet catheter, an expanding nitinol mesh or braid or other suitable material. A coiled sheet catheter may be fashioned from a flat ribbon of nitinol or other suitable material by coiling the ribbon so that proximal coils overlap and thereby constrain distal coils. When unconstrained, expandable tip portion 210 has an expanded profile and an expanded distal lumen. As shown in Figure 2b, expandable tip portion 210 may also be constrained to fit within guide catheter 206. Embolectomy device 200 may include a clot pulling device 212, comprising an elongate member 214 and wire mesh 216 or other suitable embolus capturing device. Clot pulling device 212 may include and be disposed in a microcatheter 218. In one contemplated method, retrieval sheath 204 may be disposed in guide catheter 206 so that the distal ends are approximately even and are located proximate an embolus. Clot pulling device 212 then may be inserted through sheath 204 to capture or retain the embolus. Catheter 206 then may be moved proximally so that tip portion 210 is distally disposed of guide catheter 206 and expands as shown in Figure 2d. Alternatively, retrieval sheath 204 may be moved distally relative guide catheter 206 to expand tip portion 210. Clot pulling device 212 may then be moved to position the embolus into the expanded tip portion 210. Retrieval sheath 204, and clot pulling device 212 may then be removed proximally from guide catheter 206. If desired, the embolic material may be removed from retrieval sheath 204 and clot pulling device 212 and these devices may be reintroduced into guide catheter 206. Of course other methods are contemplated. For instance, retrieval sheath 204 may be urged distally to cause tip portion 210 to expand and then clot pulling device 212 is inserted distally through retrieval sheath 204.

Figure 3 depicts an embolectomy device 100 in use in a vascular lumen 102. Device 100 includes a retrieval catheter 104 and a sheath catheter 106. Retrieval catheter 104 includes lumen 118 and may have an unconstrained state where its profile has a greater cross sectional area than the profile of sheath catheter 106 or may have a tip portion 108 having an unconstrained profile having a greater cross sectional area than the profile of sheath catheter 106. Retrieval catheter 104 also has a constrained state where it may be disposed within sheath catheter 106. Retrieval catheter 104 may be fluidly coupled to a vacuum source 116 and may include a proximally positioned manifold 110 for this purpose. Manifold may include one or more axially or radially located ports 112. Retrieval catheter includes an expandable material such as a shape memory polyurethane, nitinol coiled sheet catheter, or other suitable material. In use, retrieval catheter 104 is disposed in the lumen of sheath catheter 106 and is positioned proximate an embolus 120. Retrieval catheter 104 may be extended distally or sheath catheter 106 may be retracted proximally until a desired distal portion of retrieval catheter 104, which may include tip portion 108, is in an expanded state. Vacuum source 116 may be operated to urge embolus 120 into lumen 118. Alternatively, retrieval catheter 104 having an expanded distal portion may be positioned to capture embolus 120 in lumen 118 and vacuum source 116 may be operated to secure the embolus. Once the embolus is capture, it may be removed. This may be accomplished by retracting retrieval catheter 104 proximally into sheath catheter 106 or by extending sheath catheter 106 distally. Tip portion 108 may be fully or partially disposed within sheath catheter 106. Embolectomy device 100 may then be removed from vascular lumen 102. Alternatively, retrieval catheter 104 alone may be removed distally from sheath catheter 106. In another alternative, vacuum source 116

may be operated to remove embolus 120 distally from retrieval catheter 104. In another alternative an irrigation catheter may be used to provide fluid.

Numerous advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts or order of steps without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.